



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/091,168

03/04/2002

Duncan H. Hunter

UWA-001.01 (23433-101)

9927

25181

7590

11/05/2003

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/091,168

Applicant(s)

HUNTER ET AL.

Examin r

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1616

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 9-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter (WO 99/18053).

Hunter discloses polymer precursor compounds having the formula shown on page 4. The compounds on page 4 are directly within the scope of the claimed formula. For example, the second compound on page 4 is directly within the scope of the claimed formula when L is the first formula possible therefore, R is aryl and alkylamino. The first formula on page 4 also encompasses various claims, note that R₂ can be carbonyl group, thus encompassing claims 3-4. Also R₁ and R₂ can be various alkyl groups, as claimed. The polymer is an insoluble polymer, such as, polystyrene, which may be reacted with divinylbenzene to yield compounds of claim 15, see pages 8-9. The compounds are for preparing radiolabeled compounds, including benzamides, which are labeled with radioiodine, see page 8. The compounds may be in kit formulation and include various components therefor, filtration devices, etc., e.g., page 2. The compounds are prepared by methods as claimed, i.e., using a support for the radiolabeling procedure, etc., see pages 7-9 and the examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter (WO 99/18053) in view of Reed (US 5,746,997) and Wilbur (US 5,609,848).

Hunter discloses polymer precursor compounds having the formula shown on page 4. The precursor compounds may be used to prepare various radiolabeled compounds, but Hunter fails to specifically teach the precursor compounds for labeling compounds substituted with peptides, proteins, nucleosides or nucleotides, as claimed.

However, the use of Sn-precursors compounds for preparing radiohalogenated compounds which include peptides, nucleotides and other biomolecules are known in the art, as shown by, for example, Reed and Wilbur.

Reed teaches that Sn-substitution using Sn-derivatized precursor compounds are known be useful for labeling oligonucleotides with radioiodine to provide the advantage of yielding site-specific diagnostic agents, see abstract and columns 1-2. In column 3, precursor compounds using an aryl substituted Sn group is shown for radiohalogenating various compounds, such as, oligonucleotides, which is similar to the methods disclosed by Hunter.

Wilbur teaches that methods involving Sn-substitution of aryl compounds, similar to those disclosed by Hunter, may be employed for proteins to provide the advantage of yielding diagnostic or therapeutic agents having high specific activity, see abstract and columns 1-2.

It would have been obvious to one of ordinary skill in the art to use the improved precursor compounds and methods of Sn-substitution for radiolabeling as disclosed by Hunter for various compounds, including those having targeting agents, such as, proteins, nucleosides, etc., because Hunter teaches that the improved precursor compounds and methods may be used for various radiopharmaceuticals and it is known in the art that analogous Sn-precursor compounds and Sn substitution methods can be used for radiolabeling compounds which have such targeting agents to provide the advantage of obtaining site-specific radiopharmaceuticals, as shown by Reed and Wilbur. One of ordinary skill in the art would have been motivated to employ the improved precursor compounds and methods of radiolabeling using said precursor compounds disclosed by Hunter to provide an

Art Unit: 1616

improved means of radiolabeling radiopharmaceuticals having site-specificity, such as, those taught by Reed and Wilbur to obtain site-specific radiopharmaceuticals using improved precursors and methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,461,585. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 16 and 17 are generic to all this is recited in claims 19 of the patent. For example, the method of making the compound of claim 16 (which is dependent on claim 1) is encompassed by the second formula in claim 1 of the patent. Note, Poly-L-R-Y is present in the formula of the patented claims. Thus, claim 16 and 17 fall entirely within the scope of the patented claims, as they are generic thereto, or other words are anticipated thereby. For example, when L is the first possibility, R is aryl and Y=R₂, the patented claims encompass the pending claims. Further, the two claims are recited in somewhat reverse order, but the same radiolabeled compounds would be formed, as noted by the use of the oxidant.

Art Unit: 1616

Claim Suggestions

Claim 4 does not have a period at the end. It is suggested that the claim is amended to insert a period at the end to clearly indicate where the claim ends.

In claim 16, it is suggested that "any of" is changed to "any one of" to clearly indicate the alternative nature of the multiple dependent claim.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley
Primary Examiner
Art Unit 1616

11/4/2003